THERAGENICS CORPORATION®

K103319

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

JAN - 3 2010

Device Name:	I-Seed I-125
Device Model Number:	AgX100
Classification Name:	Radionuclide Brachytherapy Source (KXK), 21 CFR 892.5730
Device Classification:	Class II (Radiology)
Predicate Devices:	I-Seed I-125 Model I25.S06, K021343 OncoSeed Model 6711, K914281
Manufacturer:	Theragenics Corporation® 5203 Bristol Industrial Way Buford, GA 30518
Establishment Registration Number:	1037598
Official Contact:	Betsy Cortelloni Corporate Director of Quality and Regulatory Affairs Theragenics Corporation 5203 Bristol Industrial Way Buford, GA 30518 Phone: 770-831-4294 Fax: 770-831-4369 cortellb@theragenics.com

Intended Use: The brachytherapy source is intended to treat localized, unresectable tumors with low to moderate radiosensitivity. Tumors may be recurrent or residual, following external beam or excision of primary tumor.

Device Description: The I-Seed Model AgX100 is an Iodine 125 brachytherapy source. A silver rod serves as the substrate for the I-125 and as a radiopaque marker and is contained within a titanium tube sealed at both ends with a laser welded dome. The seed is 4.5 mm long and 0.8 mm in diameter.

Comparison of Technological Characteristics: The Model AgX100 is geometrically equivalent to both the Model I25.S06 and the Model 6711. The seed design is equivalent to the Model 6711.

Use Type: The brachytherapy source is single patient use. The seeds may be received sterile or non-sterile for loose or magazine loaded configurations. Non-sterile orders must be sterilized by the user facility. Custom loaded configurations are received sterile.

Sealed Source Classification: The Model AgX100 is a sealed source classified as C53211 pursuant to ISO 2919:1999E. Additionally, each source is leak-tested during manufacturing using a validated process, in accordance with internal procedures and ISO 9978:1992(E). The internal acceptance criterion for leak testing is less than 4 nCi.

Design Verification: The Model AgX100 was developed in accordance with 21 CFR 820.30 – Design Controls. Design validation and verification testing was conducted to demonstrate compliance with device performance specifications and to establish device safety.

The following standards were used in the development of the AgX100:

- ISO 2919:1999(E), Sealed Radioactive Sources - Classification
- ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: evaluation and testing
- ISO 17665-1:2006, Sterilization of healthcare products - moist heat – Part 1: Requirements for the validation and routine control of a sterilization process for medical devices
- ISO 11137-1:2006, Sterilization of healthcare products – radiation – Part 1: Requirements for the validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2006, Sterilization of healthcare products – radiation – Part 2: establishing the sterilization dose

Conclusion: The results of the V&V testing confirmed that design inputs were achieved and the cumulative test results demonstrated the functionality, safety and effectiveness of the Model AgX100, as well as its substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Betsy Cortelloni
Corporate Director of Quality and Regulatory Affairs
Theragenics Corporation, Brachytherapy Division
5203 Bristol Industrial Way
BUFORD GA 30518

JAN - 3 2010

Re: K103319
Trade/Device Name: I-Seed Model AgX100
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: November 10, 2010
Received: November 12, 2010

Dear Ms. Cortelloni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(K) number (if known): K103319

JAN - 3 2010

Device Name: I-Seed Model AgX100

Indications for Use:

The brachytherapy source is intended to treat localized, unresectable tumors with low to moderate radiosensitivity. Tumors may be recurrent or residual, following external beam or excision of primary tumor.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use_____
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103319